HFI-55 ck mp 5-12-97

DEPARTMENT OF HEALTH & HUMAN SERVICES M886N Public Health Service

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

May 7, 1997

WARNING LETTER
CIN-WL-97-326

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

E. Thomas Jezo, President & CEO
Specialized Medical Services, Inc.
933 N. Mayfair Road
Suite 309
Milwaukee, WI 53226

Dear Mr. Jezo:

During an April 2, 1997 inspection of your liquid medical oxygen transfilling facility, Medequip Home Health, located at 11527 Commonwealth Drive, Louisville, KY, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211). These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Specific observations made during the Inspection include:

(1) Failure to assay each incoming load of liquid oxygen for full USP requirements prior to filling liquid home units.

Your firm was incorrectly advised during the inspection that you could meet this requirement by receiving the liquid oxygen under a "valid" certificate of analysis. This would be true only if the bulk liquid oxygen had been received in a portable cryogenic vessel that had been assayed by the supplier, and the assay either witnessed by your employees or with a separate identity test being performed at your site.

Since your bulk liquid oxygen is received via tank truck and filled into a stand tank, the final commingled lot resulting from the mixture must be sampled from the stand tank and USP purity assay conducted, after every filling of the stand tank, prior to filling liquid home units.

(2) The particular analyzer in use by your firm is acceptable for an identity test but fails to meet the accuracy requirements necessary for USP purity assay. Your [redacted] hand held analyzer has an accuracy of ±1%. In order to equal or exceed the Orsat Method, the official USP method, your test meter must have an accuracy of at least ±0.1%.

(3) Failure to establish and maintain Batch Production and Control Records covering the filling of patient vessels.

(4) Patient vessels, which have been serviced or which are returned completely empty, do not receive full USP testing for oxygen purity after filling and before delivery to patient homes.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 684-3501.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

cc: James C. Holbrook,
Chief Operating Officer
Medequip Home Health
11527 Commonwealth Drive
Louisville, KY 40299